EXHIBIT A

REDACTED

EXHIBIT B

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EXHIBIT C

REDACTED

EXHIBIT D

US006241762B1

(12) **United States Patent**
Shanley

(10) **Patent No.: US 6,241,762 B1**
(45) **Date of Patent: Jun. 5, 2001**

(54) **EXPANDABLE MEDICAL DEVICE WITH DUCTILE HINGES**

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(73) Assignee: **Conor Medsystems, Inc.**, Redwood City, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/183,555**

(22) Filed: **Oct. 29, 1998**

Related U.S. Application Data

(60) Provisional application No. 60/079,881, filed on Mar. 30, 1998.

(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1.17**; 623/1.18

(58) **Field of Search** 623/1, 11, 12, 623/1.11, 1.12, 1.15, 1.17, 1.18, 1.19, 1.2, 1.27, 1.28, 1.3, 1.34; 606/108, 191, 194, 195

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Primary Examiner—V. Millin
Assistant Examiner—Tram A. Nguyen
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(57) **ABSTRACT**

An expandable tissue supporting device of the present invention employs ductile hinges at selected points in the expandable device. When expansion forces are applied to the device as a whole, the ductile hinges concentrate expansion stresses and strains in small well defined areas. The expandable medical device including ductile hinges provides the advantages of low expansion force requirements, relatively thick walls which are radio-opaque, improved crimping properties, high crush strength, reduced elastic recoil after implantation, and control of strain to a desired level. The expandable tissue supporting device includes a plurality of elongated beams arranged in a cylindrical device and connected together by a plurality of ductile hinges. Although many ductile hinge configurations are possible, the ductile hinges preferably have a substantially constant hinge cross sectional area which is smaller than a beam cross sectional area such that as the device is expanded from a first diameter to a second diameter, the ductile hinges experience plastic deformation while the beams are not plastically deformed.

31 Claims, 9 Drawing Sheets

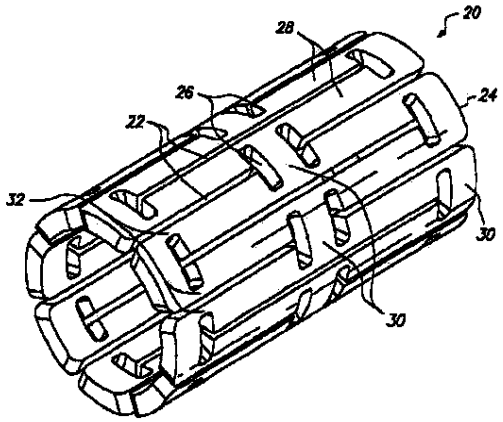

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FIG. 1
PRIOR ART

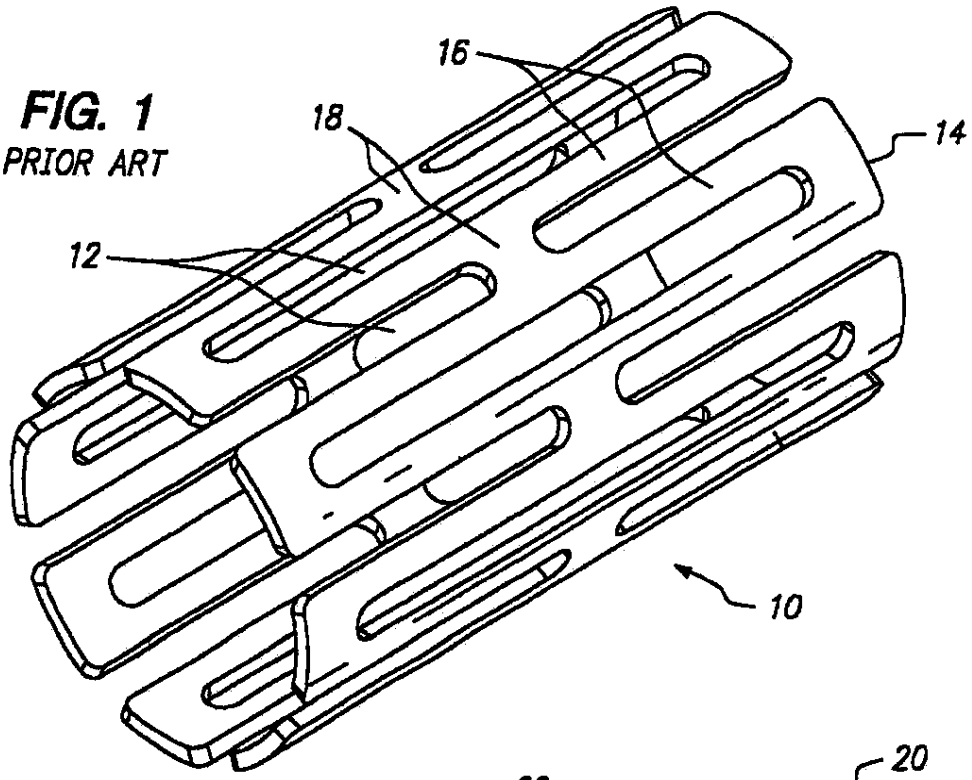
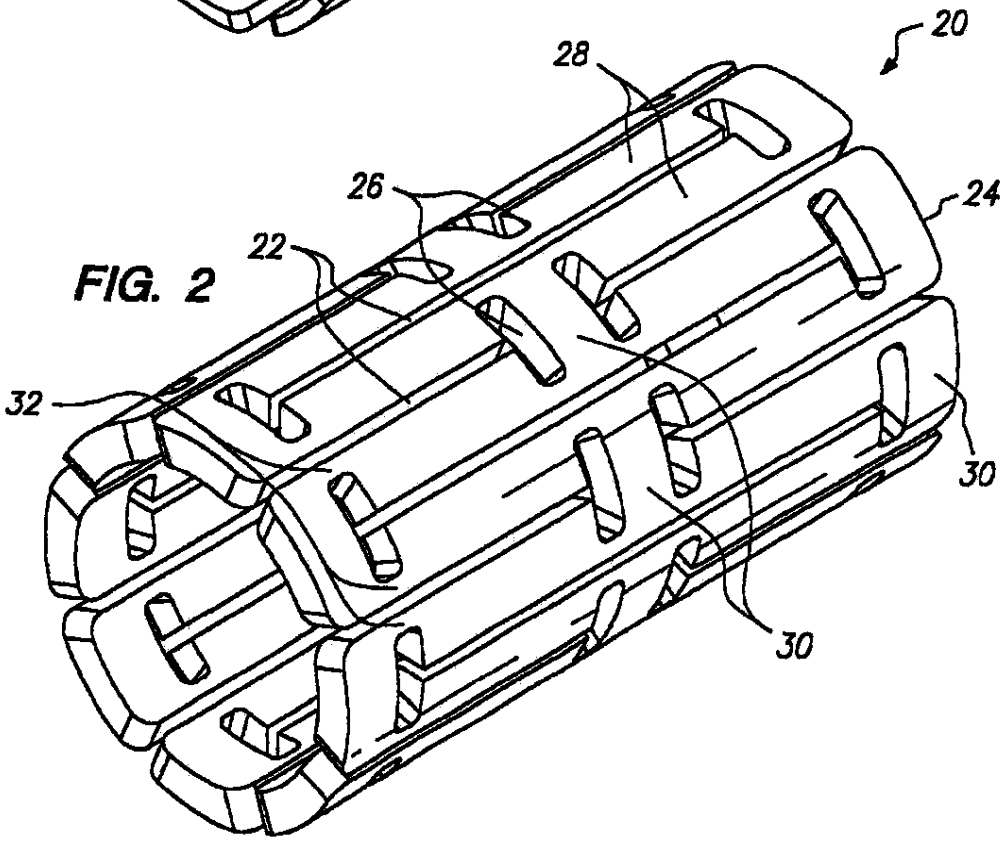


FIG. 2



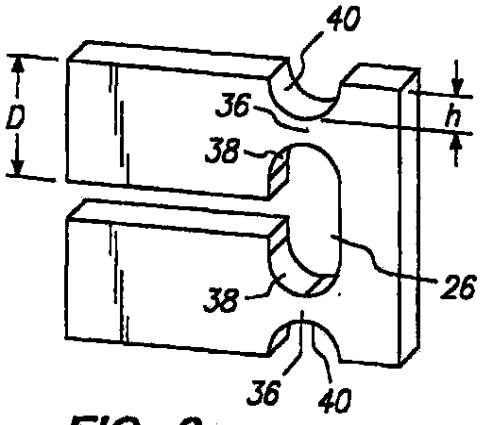


FIG. 3a

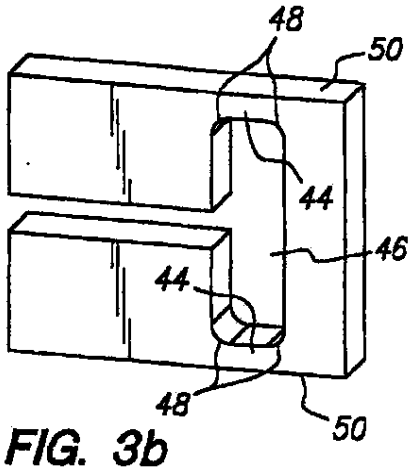


FIG. 3b

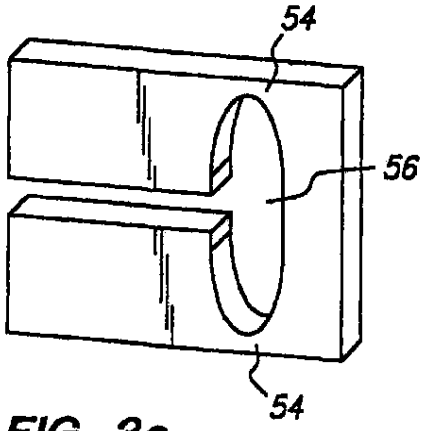


FIG. 3c

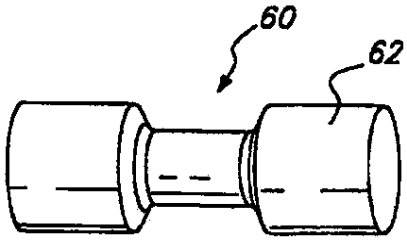


FIG. 3d

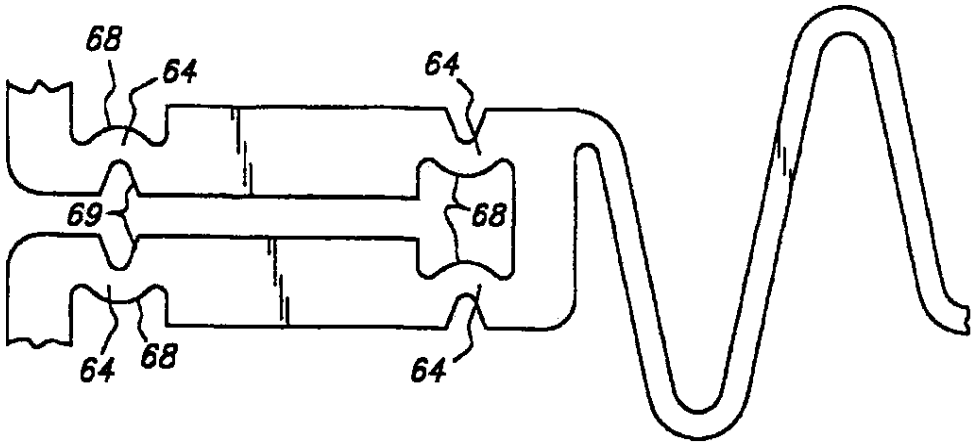


FIG. 3e

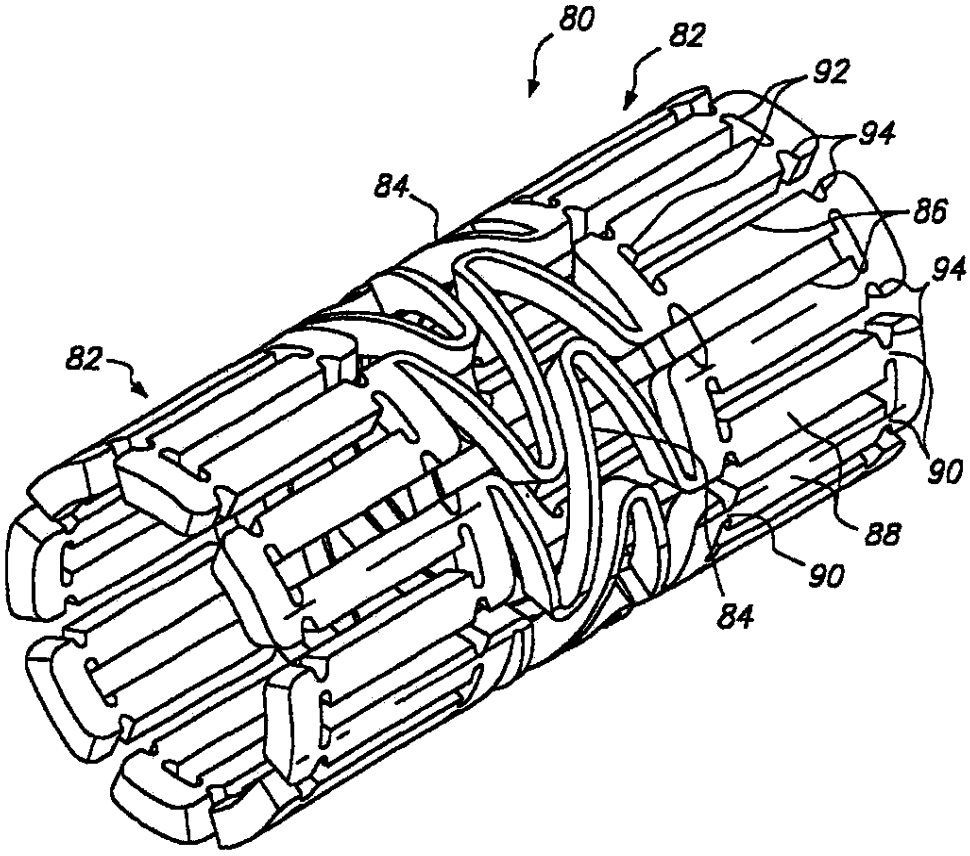


FIG. 4a

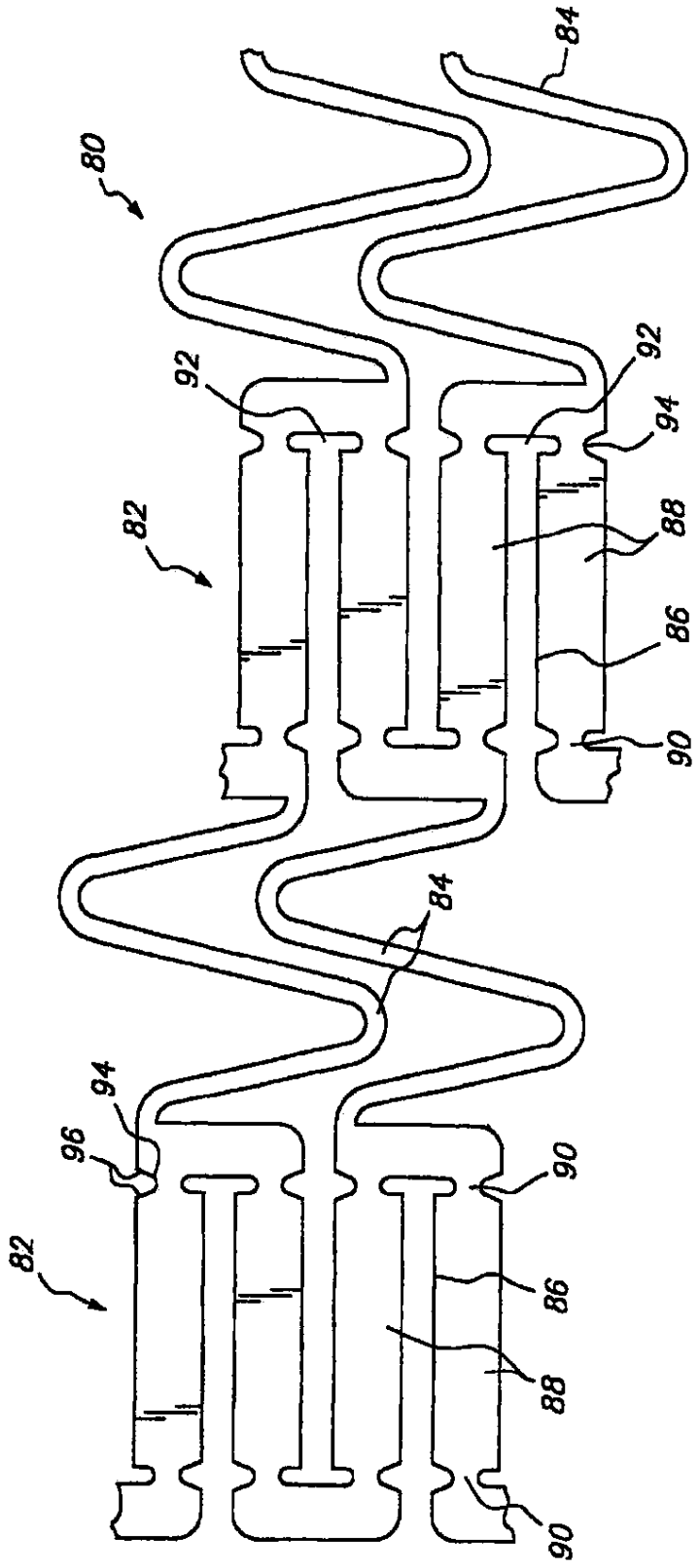


FIG. 4b

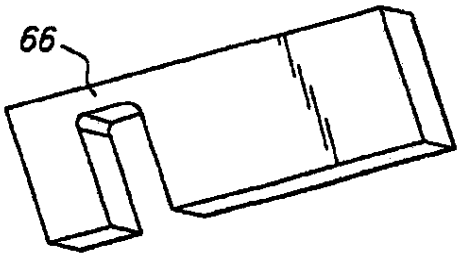


FIG. 5a

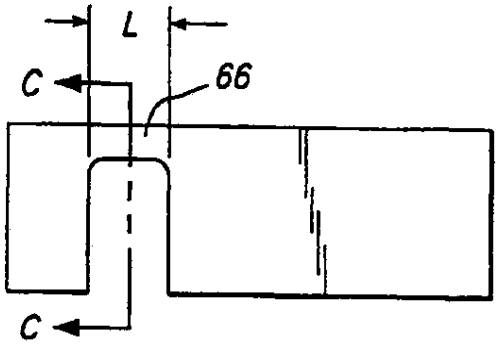


FIG. 5b

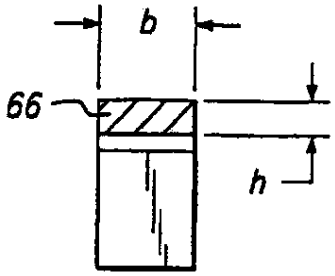


FIG. 5c

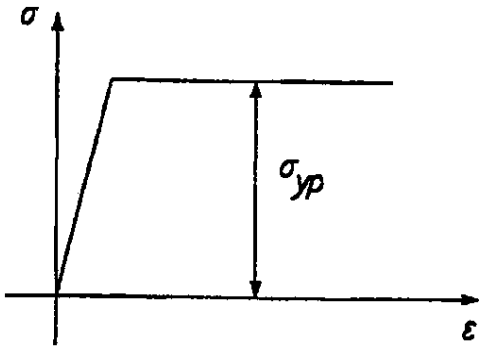


FIG. 5d

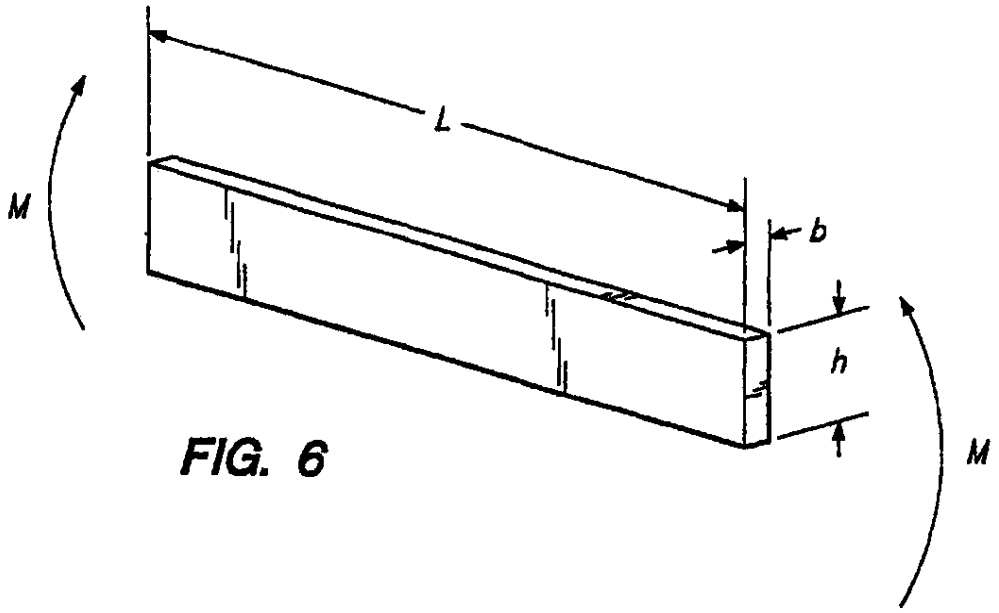

L
M
b
h
M

FIG. 6

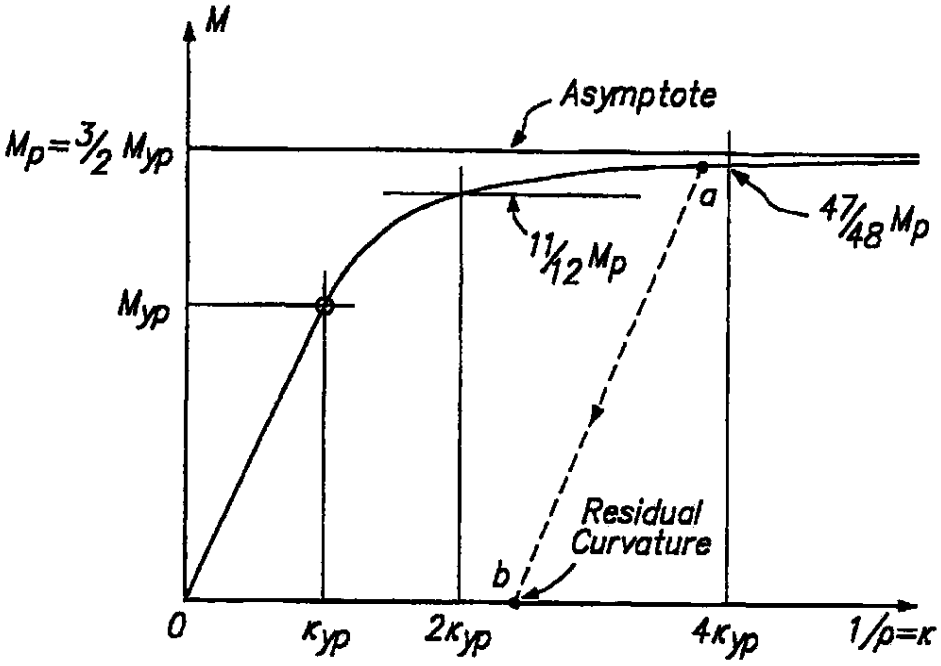

M
Asymptote
$M_p = 3/2\ M_{yp}$
$11/12\ M_p$
$47/48\ M_p$
a
M_{yp}
Residual Curvature
b
0
κ_{yp}
$2\kappa_{yp}$
$4\kappa_{yp}$
$1/\rho = \kappa$

FIG. 7

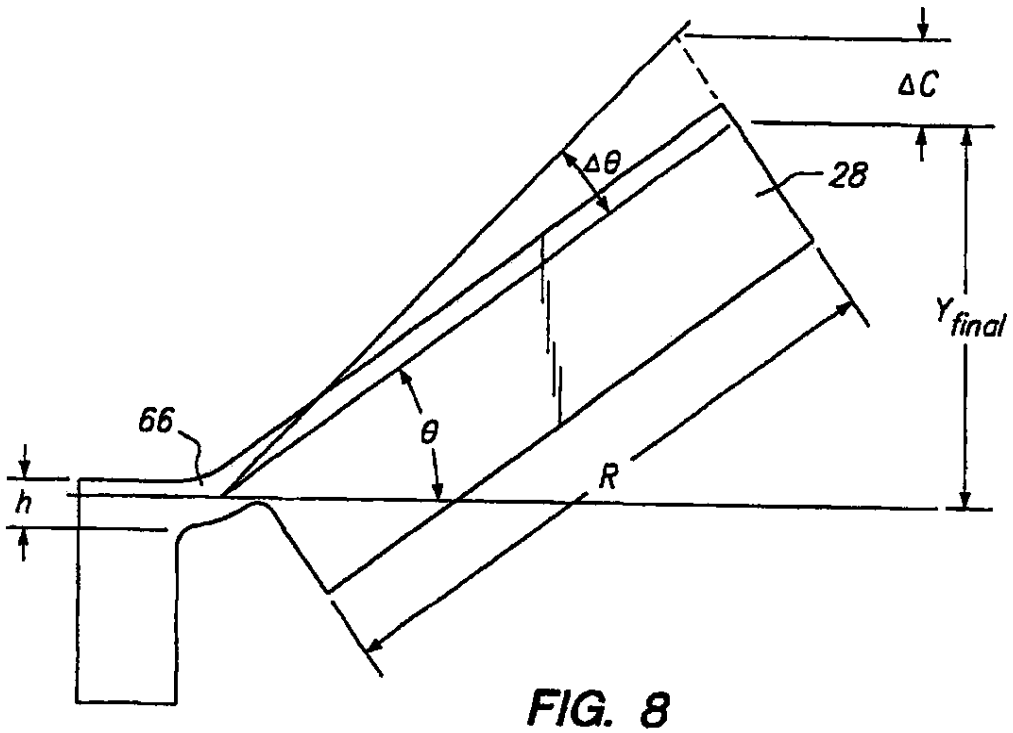


FIG. 8

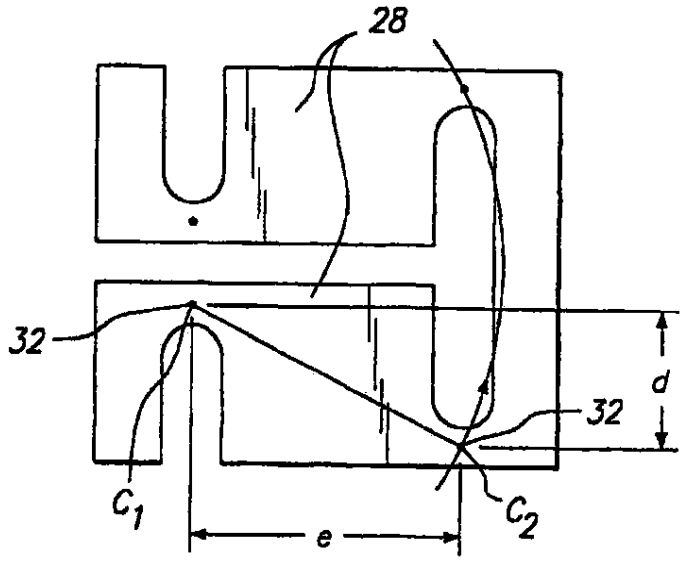


FIG. 9a

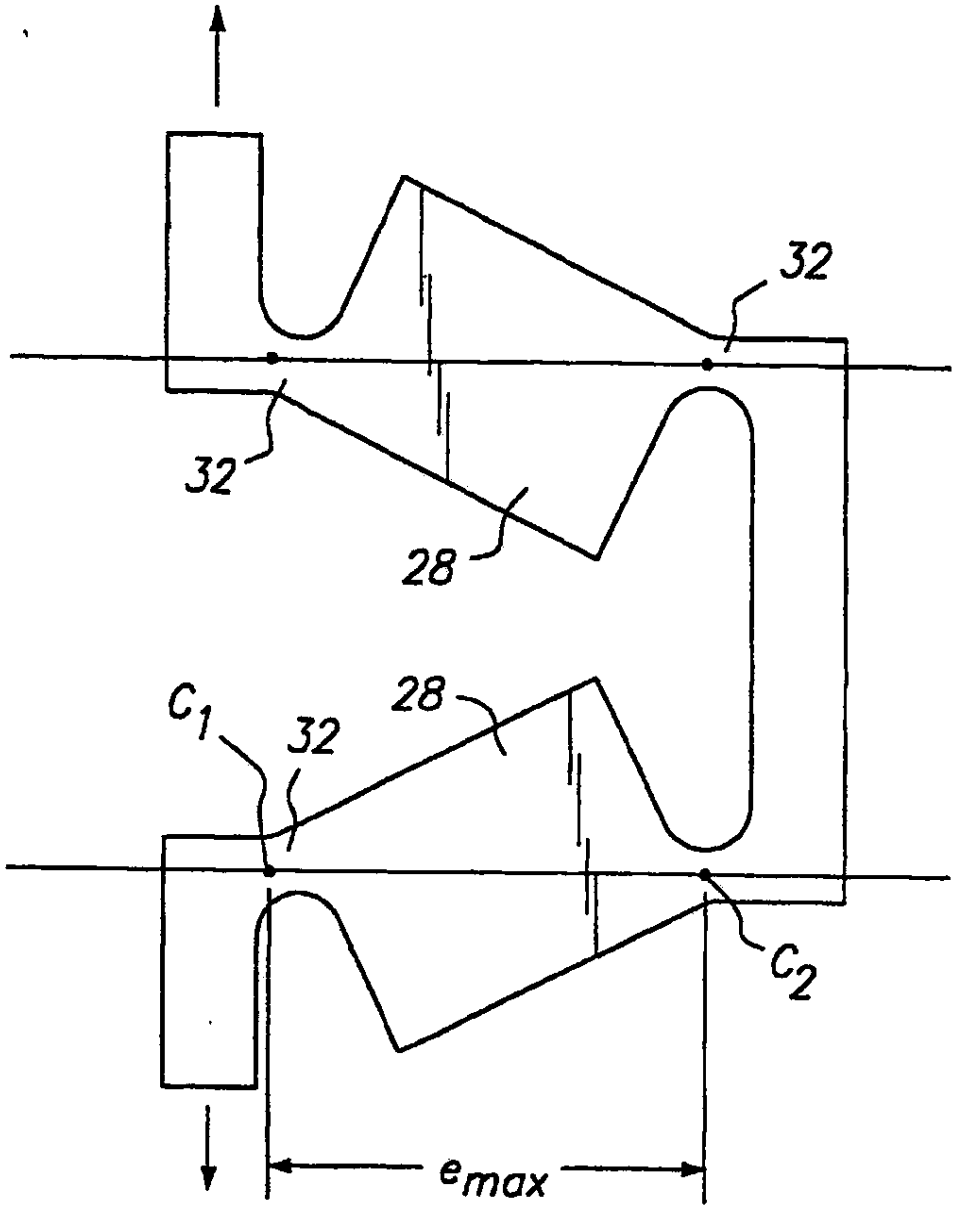


FIG. 9b

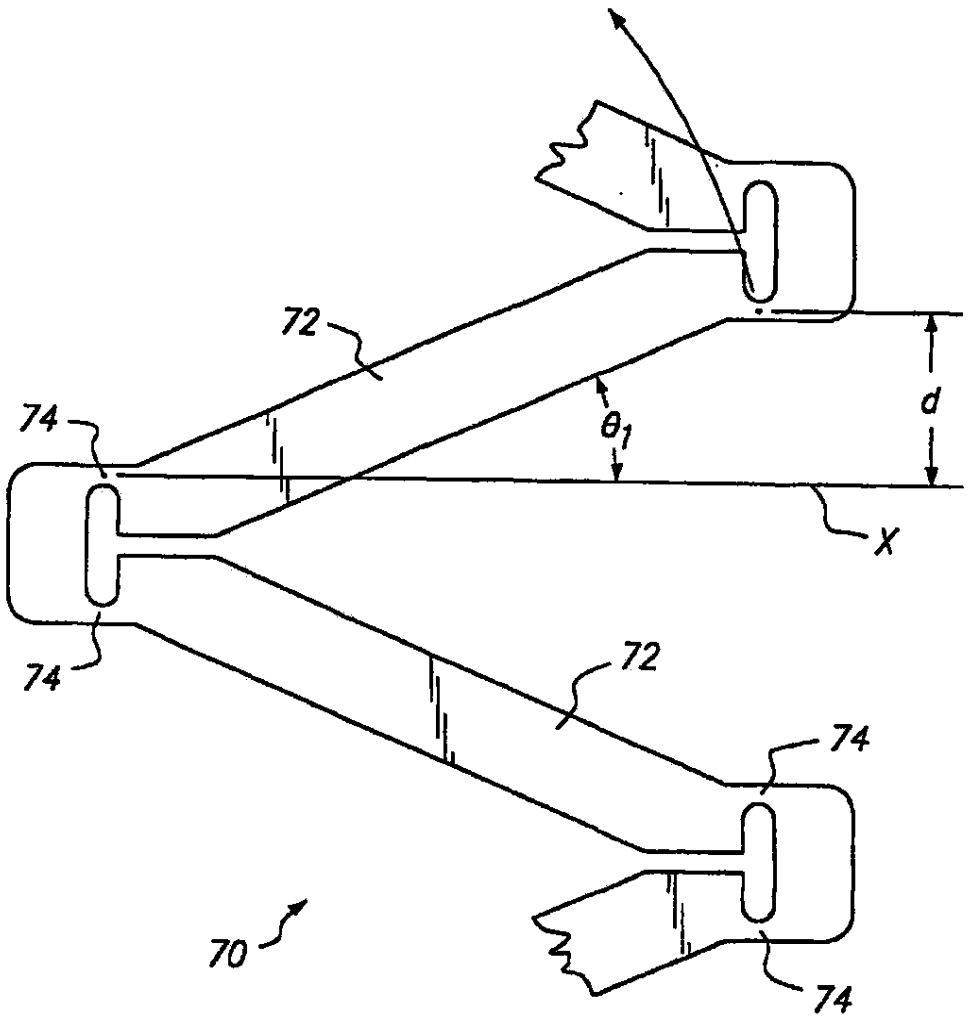


FIG. 10

EXPANDABLE MEDICAL DEVICE WITH DUCTILE HINGES

This appln claims the benefit of Provisional No. 60/079,881 filed Mar. 30, 1998.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to tissue-supporting medical devices, and more particularly to expandable, non-removable devices that are implanted within a bodily lumen of a living animal or human to support the organ and maintain patency.

2. Summary of the Related Art

In the past, permanent or biodegradable devices have been developed for implantation within a body passageway to maintain patency of the passageway. These devices are typically introduced percutaneously, and transported transluminally until positioned at a desired location. These devices are then expanded either mechanically, such as by the expansion of a mandrel or balloon positioned inside the device, or expand themselves by releasing stored energy upon actuation within the body. Once expanded within the lumen, these devices, called stents, become encapsulated within the body tissue and remain a permanent implant.

Known stent designs include monofilament wire coil stents (U.S. Pat. No. 4,969,458); welded metal cages (U.S. Pat. Nos. 4,733,665 and 4,776,337); and, most prominently, thin-walled metal cylinders with axial slots formed around the circumference (U.S. Pat. Nos. 4,733,665, 4,739,762, and 4,776,337). Known construction materials for use in stents include polymers, organic fabrics and biocompatible metals, such as, stainless steel, gold, silver, tantalum, titanium, and shape memory alloys such as Nitinol.

U.S. Pat. Nos. 4,733,665, 4,739,762, and 4,776,337 disclose expandable and deformable interluminal vascular grafts in the form of thin-walled tubular members with axial slots allowing the members to be expanded radially outwardly into contact with a body passageway. After insertion, the tubular members are mechanically expanded beyond their elastic limit and thus permanently fixed within the body. The force required to expand these tubular stents is proportional to the thickness of the wall material in a radial direction. To keep expansion forces within acceptable levels for use within the body (e.g., 5–10 atm), these designs must use very thin-walled materials (e.g., stainless steel tubing with 0.0025 inch thick walls). However, materials this thin are not visible on conventional fluoroscopic and x-ray equipment and it is therefore difficult to place the stents accurately or to find and retrieve stents that subsequently become dislodged and lost in the circulatory system.

Further, many of these thin-walled tubular stent designs employ networks of long, slender struts whose width in a circumferential direction is two or more times greater than their thickness in a radial direction. When expanded, these struts are frequently unstable, that is, they display a tendency to buckle, with individual struts twisting out of plane. Excessive protrusion of these twisted struts into the bloodstream has been observed to increase turbulence, and thus encourage thrombosis. Additional procedures have often been required to attempt to correct this problem of buckled struts. For example, after initial stent implantation is determined to have caused buckling of struts, a second, high-pressure balloon (e.g., 12 to 18 atm) would be used to attempt to drive the twisted struts further into the lumen wall. These secondary procedures can be dangerous to the patient due to the risk of collateral damage to the lumen wall.

Many of the known stents display a large elastic recovery, known in the field as "recoil," after expansion inside a lumen. Large recoil necessitates over-expansion of the stent during implantation to achieve the desired final diameter. Over-expansion is potentially destructive to the lumen tissue. Known stents of the type described above experience recoil of up to about 6 to 12% from maximum expansion.

Large recoil also makes it very difficult to securely crimp most known stents onto delivery catheter balloons. As a result, slippage of stents on balloons during interlumenal transportation, final positioning, and implantation has been an ongoing problem. Many ancillary stent securing devices and techniques have been advanced to attempt to compensate for this basic design problem. Some of the stent securing devices include collars and sleeves used to secure the stent onto the balloon.

Another problem with known stent designs is non-uniformity in the geometry of the expanded stent. Non-uniform expansion can lead to non-uniform coverage of the lumen wall creating gaps in coverage and inadequate lumen support. Further, over expansion in some regions or cells of the stent can lead to excessive material strain and even failure of stent features. This problem is potentially worse in low expansion force stents having smaller feature widths and thicknesses in which manufacturing variations become proportionately more significant. In addition, a typical delivery catheter for use in expanding a stent includes a balloon folded into a compact shape for catheter insertion. The balloon is expanded by fluid pressure to unfold the balloon and deploy the stent. This process of unfolding the balloon causes uneven stresses to be applied to the stent during expansion of the balloon due to the folds causing the problem non-uniform stent expansion.

U.S. Pat. No. 5,545,210 discloses a thin-walled tubular stent geometrically similar to those discussed above, but constructed of a nickel-titanium shape memory alloy ("Nitinol"). This design permits the use of cylinders with thicker walls by making use of the lower yield stress and lower elastic modulus of martensitic phase Nitinol alloys. The expansion force required to expand a Nitinol stent is less than that of comparable thickness stainless steel stents of a conventional design. However, the "recoil" problem after expansion is significantly greater with Nitinol than with other materials. For example, recoil of a typical design Nitinol stent is about 9%. Nitinol is also more expensive, and more difficult to fabricate and machine than other stent materials, such as stainless steel.

All of the above stents share a critical design property: in each design, the features that undergo permanent deformation during stent expansion are prismatic, i.e., the cross sections of these features remain constant or change very gradually along their entire active length. To a first approximation, such features deform under transverse stress as simple beams with fixed or guided ends: essentially, the features act as a leaf springs. These leaf spring like structures are ideally suited to providing large amounts of elastic deformation before permanent deformation commences. This is exactly the opposite of ideal stent behavior. Further, the force required to deflect prismatic stent struts in the circumferential direction during stent expansion is proportional to the square of the width of the strut in the circumferential direction. Expansion forces thus increase rapidly with strut width in the above stent designs. Typical expansion pressures required to expand known stents are between about 5 and 10 atmospheres. These forces can cause substantial damage to tissue if misapplied.

FIG. 1 shows a typical prior art "expanding cage" stent design. The stent 10 includes a series of axial slots 12

formed in a cylindrical tube **14**. Each axial row of slots **12** is displaced axially from the adjacent row by approximately half the slot length providing a staggered slot arrangement. The material between the slots **12** forms a network of axial struts **16** joined by short circumferential links **18**. The cross section of each strut **16** remains constant or varies gradually along the entire length of the strut and thus the rectangular moment of inertia and the elastic and plastic section moduli of the cross section also remain constant or vary gradually along the length of the strut. Such a strut **16** is commonly referred to as a prismatic beam. Struts **16** in this type of design are typically 0.005 to 0.006 inches (0.127–0.1524 mm) wide in the circumferential direction. Strut thicknesses in the radial direction are typically about 0.0025 inches (0.0635 mm) or less to keep expansion forces within acceptable levels. However, most stent materials must be approximately 0.005 inches (0.127 mm) thick for good visibility on conventional fluoroscopic equipment. This high ratio of strut width to thickness, combined with the relatively high strut length and the initial curvature of the stent tubing combine to cause the instability and bucking often seen in this type of stent design. When expanded, the stent structure of FIG. **1** assumes the roughly diamond pattern commonly seen in expanded sheet metal.

Another stent described in PCT publication number WO 96/29028 uses struts with relatively weak portions of-locally-reduced cross sections which on expansion of the stent act to concentrate deformation at these areas. However, as discussed above non-uniform expansion is even more of a problem when smaller feature widths and thicknesses are involved because manufacturing variations become proportionately more significant. The locally-reduced cross section portions described in this document are formed by pairs of circular holes. The shape of the locally-reduced cross section portions undesirably concentrates the plastic strain at the narrowest portion. This concentration of plastic strain without any provision for controlling the level of plastic strain makes the stent highly vulnerable to failure.

In view of the drawbacks of the prior art stents, it would be advantageous to be able to expand a stent with an expansion force at a low level independent of choice of stent materials, material thickness, or strut dimensions.

It would further be advantageous to have a tissue-supporting device that permits a choice of material thickness that could be viewed easily on conventional fluoroscopic equipment for any material.

It would also be advantageous to have a tissue-supporting device that is inherently stable during expansion, thus eliminating buckling and twisting of structural features during stent deployment.

It would also be desirable to control strain to a desired level which takes advantage of work hardening without approaching a level of plastic strain at which failure may occur.

In addition, it would be advantageous to have a tissue-supporting device with minimal elastic recovery, or "recoil" of the device after expansion.

It would be advantageous to have a tissue supporting device that can be securely crimped to the delivery catheter without requiring special tools, techniques, or ancillary clamping features.

It would further be advantageous to have a tissue-supporting device that has improved resistance to compressive forces (improved crush strength) after expansion.

It would also be advantageous to have a tissue-supporting device that achieves all the above improvements with minimal foreshortening of the overall stent length during expansion.

SUMMARY OF THE INVENTION

The present invention addresses several important problems in expandable medical device design including: high expansion force requirements; lack of radio-opacity in thin-walled stents; buckling and twisting of stent features during expansion; poor crimping properties; and excessive elastic recovery ("recoil") after implantation. The invention also provides benefits of improved resistance to compressive forces after expansion, control of the level of plastic strain, and low axial shortening during expansion. Some embodiments of the invention also provide improved uniformity of expansion by limiting a maximum geometric deflection between struts. The invention may also incorporate sites for the inclusion of beneficial agent delivery.

The invention involves the incorporation of stress/strain concentration features or "ductile hinges" at selected points in the body of an expandable cylindrical medical device. When expansion forces are applied to the device as a whole, these ductile hinges concentrate expansion stresses and strains in small, well-defined areas while limiting strut deflection and plastic strain to specified levels.

In accordance with one aspect of the present invention, an expandable medical device includes a plurality of elongated beams having a substantially constant beam cross sectional area along a beam length. The plurality of elongated beams are joined together to form a substantially cylindrical device which is expandable from a cylinder having a first diameter to a cylinder having a second diameter. A plurality of ductile hinges connect the plurality of beams together in the substantially cylindrical device. The ductile hinges have a substantially constant hinge cross sectional area along a substantial portion of a hinge length. The hinge cross sectional area is smaller than the beam cross sectional area such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed.

In accordance with a further aspect of the invention, an expandable medical device includes a cylindrical tube, and a plurality of axial slots formed in the cylindrical tube in a staggered arrangement to define a network of elongated struts, wherein each of the elongated struts are axially displaced from adjacent struts. A plurality of ductile hinges are formed between the elongated struts. The ductile hinges allow the cylindrical tube to be expanded or compressed from a first diameter to a second diameter by deformation of the ductile hinges. The ductile hinges are asymmetrically configured to reach a predetermined strain level upon a first percentage expansion and to reach the predetermined strain level upon a second percentage of compression, wherein the first percentage is larger than the second percentage.

In accordance with another aspect of the present invention, an expandable medical device includes a plurality of elongated beams having a substantially constant beam cross sectional area along a beam length. A plurality of ductile hinges connect the plurality of beams together in a substantially cylindrical device which is expandable or compressible from a first diameter to a second diameter by plastic deformation of the ductile hinges. A plurality of deflection limiting members are positioned at a plurality of the ductile hinges which limit the deflection at the ductile hinges.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

an opposite end surface. A plurality of axial struts **88** having ductile hinges **90** are formed between the axial slots **86**. The ductile hinges **90** are formed by circumferential slots **92** formed at the interior ends of the axial slots **86** and opposed notches **94**.

The notches **94** each have two opposed angled walls **96** which function as a stop to limit geometric deflection of the ductile hinge, and thus limit maximum device expansion. As the cylindrical tubes **82** are expanded and bending occurs at the ductile hinges **90**, the angled side walls **96** of the notches **94** move toward each other. Once the opposite side walls **96** of a notch come into contact with each other, they resist further expansion of the particular ductile hinge causing further expansion to occur at other sections of the tissue supporting device. This geometric deflection limiting feature is particularly useful where uneven expansion is caused by either variations in the tissue supporting device **80** due to manufacturing tolerances or uneven balloon expansion.

The tissue supporting device **20, 80** according to the present invention may be formed of any ductile material, such as steel, gold, silver, tantalum, titanium, Nitinol, other shape memory alloys, other metals, or even some plastics. One preferred method for making the tissue supporting device **20, 80** involves forming a cylindrical tube and then laser cutting the slots **22, 26, 86, 92** and notches **94** into the tube. Alternatively, the tissue supporting device may be formed by electromachining, chemical etching followed by rolling and welding, or any other known method.

The design and analysis of stress/strain concentration for ductile hinges, and stress/strain concentration features in general, is complex. For example, the stress concentration factor for the simplified ductile hinge geometry of FIG. **3***a* can be calculated and is given by the following expression where D is the width of the struts **28**, h is the height of the circular grooves **38, 40**, and r is the radius of curvature of the grooves. For purposes of this example the ratio of h/r is taken to be 4. However, other ratios of h/r can also be implemented successfully.

$$K = 4.935 - 7.586\left(\frac{2h}{D}\right) + 0.515\left(\frac{2h}{D}\right)^2 + 0.432\left(\frac{2h}{D}\right)^3$$

The stress concentration factors are generally useful only in the linear elastic range. Stress concentration patterns for a number of other geometries can be determined through photoelastic measurements and other experimental methods. Stent designs based on the use of stress/strain concentration features, or ductile hinges, generally involve more complex hinge geometries and operate in the non-linear elastic and plastic deformation regimes.

The general nature of the relationship among applied forces, material properties, and ductile hinge geometry can be more easily understood through analysis of an idealized hinge **66** as shown in FIGS. **5***a*–*5c*. The hinge **66** is a simple beam of rectangular cross section having a width h, length L and thickness b. The idealized hinge **66** has elastic-ideally-plastic material properties which are characterized by the ideal stress/strain curve of FIG. **5***d*. It can be shown that the "plastic" or "ultimate bending moment" for such a beam is given by the expression:

$$M_p = M_{ult} = \delta_{yp}\frac{bh^2}{4}$$

Where b corresponds to the cylindrical tube wall thickness, h is the circumferential width of the ductile hinge, and δ_{yp} is the yield stress of the hinge material. Assuming only that expansion pressure is proportional to the plastic moment, it can be seen that the required expansion pressure to expand the tissue supporting device increases linearly with wall thickness b and as the square of ductile hinge width h. It is thus possible to compensate for relatively large changes in wall thickness b with relatively small changes in hinge width h. While the above idealized case is only approximate, empirical measurements of expansion forces for different hinge widths in several different ductile hinge geometries have confirmed the general form of this relationship. Accordingly, for different ductile hinge geometries it is possible to increase the thickness of the tissue supporting device to achieve radiopacity while compensating for the increased thickness with a much smaller decrease in hinge width.

Ideally, the stent wall thickness b should be as thin as possible while still providing good visibility on a fluoroscope. For most stent materials, including stainless steel, this would suggest a thickness of about 0.005–0.007 inches (0.127–0.178 mm) or greater. The inclusion of ductile hinges in a stent design can lower expansion forces/pressures to very low levels for any material thickness of interest. Thus ductile hinges allow the construction of optimal wall thickness tissue supporting devices at expansion force levels significantly lower than current non-visible designs.

The expansion forces required to expand the tissue supporting device **20** according to the present invention from an initial condition illustrated in FIG. **2** to an expanded condition is between 1 and 5 atmospheres, preferably between 2 and 3 atmospheres. The expansion may be performed in a known manner, such as by inflation of a balloon or by a mandrel. The tissue supporting device **20** in the expanded condition has a diameter which is preferably up to three times the diameter of the device in the initial unexpanded condition.

Many tissue supporting devices fashioned from cylindrical tubes comprise networks of long, narrow, prismatic beams of essentially rectangular cross section as shown in FIG. **6**. These beams which make up the known tissue supporting devices may be straight or curved, depending on the particular design. Known expandable tissue supporting devices have a typical wall thickness b of 0.0025 inches (0.0635 mm), and a typical strut width h of 0.005 to 0.006 inches (0.127–0.1524 mm). The ratio of b:h for most known designs is 1:2 or lower. As b decreases and as the beam length L increases, the beam is increasingly likely to respond to an applied bending moment M by buckling, and many designs of the prior art have displayed this behavior. This can be seen in the following expression for the "critical buckling moment" for the beam of FIG. **6**.

$$M_{cru} = \frac{\pi b^3 h\sqrt{EG(1-0.63\,b/h)}}{6L}$$

Where:

E=Modulus of Elasticity

G=Shear Modulus

By contrast, in a ductile hinge based design according to the present invention, only the hinge itself deforms during expansion. The typical ductile hinge **32** is not a long narrow beam as are the struts in the known stents. Wall thickness of the present invention may be increased to 0.005 inches (0.127 mm) or greater, while hinge width is typically 0.002–0.003 inches (0.0508–0.0762 mm), preferably 0.0025 inches (0.0635 mm) or less. Typical hinge length, at 0.002

to 0.005 inches (0.0508–0.0127 mm), is more than an order of magnitude less than typical strut length. Thus, the ratio of b:h in a typical ductile hinge **32** is 2:1 or greater. This is an inherently stable ratio, meaning that the plastic moment for such a ductile hinge beam is much lower than the critical buckling moment M_{crip} and the ductile hinge beam deforms through normal strain-curvature. Ductile hinges **32** are thus not vulnerable to buckling when subjected to bending moments during expansion of the tissue supporting device **20**.

To provide optimal recoil and crush-strength properties, it is desirable to design the ductile hinges so that relatively large strains, and thus large curvatures, are imparted to the hinge during expansion of the tissue supporting device. Curvature is defined as the reciprocal of the radius of curvature of the neutral axis of a beam in pure bending. A larger curvature during expansion results in the elastic curvature of the hinge being a small fraction of the total hinge curvature. Thus, the gross elastic recoil of the tissue supporting device is a small fraction of the total change in circumference. It is generally possible to do this because common stent materials, such as 316L Stainless Steel have very large elongations-to-failure (i.e., they are very ductile).

It is not practical to derive exact expressions for residual curvatures for complex hinge geometries and real materials (i.e., materials with non-idealized stress/strain curves). The general nature of residual curvatures and recoil of a ductile hinge may be understood by examining the moment-curvature relationship for the elastic-ideally-plastic rectangular hinge **66** shown in FIGS. **5***a–c*. It may be shown that the relationship between the applied moment and the resulting beam curvature is:

$$M = M_p\left[1 - \frac{1}{3}\left(\frac{\gamma_o}{h/2}\right)^2\right] = 3/2M_{yp}\left[1 - \frac{1}{3}\left(\frac{\kappa_{yp}}{\kappa}\right)^2\right]$$

This function is plotted in FIG. **7**. It may be seen in this plot that the applied moment M asymptotically approaches a limiting value M_p, called the plastic or ultimate moment. Beyond 11½ M_p large plastic deformations occur with little additional increase in applied moment. When the applied moment is removed, the beam rebounds elastically along a line such as a-b. Thus, the elastic portion of the total curvature approaches a limit of 3/2 the curvature at the yield point. These relations may be expressed as follows:

$$M_p = \frac{3}{2}M_{yp} \Rightarrow \kappa_{rebound} = \frac{3}{2}\kappa_{yp}$$

Imparting additional curvature in the plastic zone cannot further increase the elastic curvature, but will decrease the ratio of elastic to plastic curvature. Thus, additional curvature or larger expansion of the tissue supporting device will reduce the percentage recoil of the overall stent structure.

As shown in FIG. **8**, when a rigid strut **28** is linked to the ductile hinge **66** described above, the strut **28** forms an angle θ with the horizontal that is a function of hinge curvature. A change in hinge curvature results in a corresponding change in this angle θ. The angular elastic rebound of the hinge is the change in angle Δθ that results from the rebound in elastic curvature described above, and thus angular rebound also approaches a limiting value as plastic deformation proceeds. The following expression gives the limiting value of angular elastic rebound for the idealized hinge of FIG. **8**.

$$\theta_{rebound} = 3\varepsilon_{yp}\frac{L}{h}$$

Where strain at the yield point is an independent material property (yield stress divided by elastic modulus); L is the length of the ductile hinge; and h is the width of the hinge. For non-idealized ductile hinges made of real materials, the constant 3 in the above expression is replaced by a slowly rising function of total strain, but the effect of geometry would remain the same. Specifically, the elastic rebound angle of a ductile hinge decreases as the hinge width h increases, and increases as the hinge length L increases. To minimize recoil, therefore, hinge width h should be increased and length L should be decreased.

Ductile hinge width h will generally be determined by expansion force criteria, so it is important to reduce hinge length to a practical minimum in order to minimize elastic rebound. Empirical data on recoil for ductile hinges of different lengths show significantly lower recoil for shorter hinge lengths, in good agreement with the above analysis.

The ductile hinges **32** of the tissue supporting device **20** provide a second important advantage in minimizing device recoil. The embodiment of FIG. **2** shows a network of struts joined together through ductile hinges to form a cylinder. In this design, the struts **28** are initially parallel to an axis of the device. As the device is expanded, curvature is imparted to the hinges **32**, and the struts **28** assume an angle θ with respect to their original orientation, as shown in FIG. **8**. The total circumferential expansion of the tissue supporting device structure is a function of hinge curvature (strut angle) and strut length. Moreover, the incremental contribution to stent expansion (or recoil) for an individual strut depends on the instantaneous strut angle. Specifically, for an incremental change in strut angle Δθ, the incremental change in circumference ΔC will depend on the strut length R and the cosine of the strut angle θ.

$$\Delta C = R\Delta\theta\cos\theta$$

Since elastic rebound of hinge curvature is nearly constant at any gross curvature, the net contribution to circumferential recoil ΔC is lower at higher strut angles θ. The final device circumference is usually specified as some fixed value, so decreasing overall strut length can increase the final strut angle θ. Total stent recoil can thus be minimized with ductile hinges by using shorter struts and higher hinge curvatures when expanded.

Empirical measurements have shown that tissue supporting device designs based on ductile hinges, such as the embodiment of FIG. **2**, display superior resistance to compressive forces once expanded despite their very low expansion force. This asymmetry between compressive and expansion forces may be due to a combination of factors including the geometry of the ductile hinge, the increased wall thickness, and increased work hardening due to higher strain levels.

According to one example of the tissue supporting device of the invention, the device can be expanded by application of an internal pressure of about 2 atmospheres or less, and once expanded to a diameter between 2 and 3 times the initial diameter can withstand a compressive force of about 16 to 20 gm/mm or greater. Examples of typical compression force values for prior art devices are 3.8 to 4.0 gm/mm.

While both recoil and crash strength properties of tissue supporting devices can be improved by use of ductile hinges

with large curvatures in the expanded configuration, care must be taken not to exceed an acceptable maximum strain level for the material being used. For the ductile hinge **44** of FIG. **3***b*, for example, it may be shown that the maximum material strain for a given bend angle is given by the expression:

$$\epsilon_{max} = \frac{h\theta}{L2}$$

Where ϵ_{max} is maximum strain, h is ductile hinge width, L is ductile hinge length and θ is bend angle in radians When strain, hinge width and bend angle are determined through other criteria, this expression can be evaluated to determine the correct ductile hinge length L.

For example, suppose the ductile hinge **44** of FIG. **3***b* was to be fabricated of 316L stainless steel with a maximum strain of 30%; ductile hinge width h is set at 0.0025 inch (0.0635 mm) by expansion force criteria; and the bend angle θ is mechanically limited to 0.5 radians (≈30%) at full stent expansion. Solving the above expression for L gives the required ductile hinge length of at least about 0.0033 inches (0.0838 mm).

Similar expressions may be developed to determine required lengths for more complicated ductile hinge geometries, such as shown in FIG. **3***e*. Typical values for the prismatic portions of these curved ductile hinges range from about 0.002 to about 0.0035 inches (0.051–0.089 mm) in hinge width and about 0.002 to about 0.006 inches (0.051–0.152 mm) in hinge length. The tissue supporting device design of FIGS. **4***a* and **4***b* include a stop which limits the maximum geometric deflection at the ductile hinges by the design of the angled walls **96** of the notches **94**.

In many designs of the prior art, circumferential expansion was accompanied by a significant contraction of the axial length of the stent which may be up to 15% of the initial device length. Excessive axial contraction can cause a number of problems in device deployment and performance including difficulty in proper placement and tissue damage. Designs based on ductile hinges **32** can minimize the axial contraction, or foreshortening, of a tissue supporting device during expansion as follows.

FIGS. **9***a* and **9***b* illustrate an exaggerated ductile hinge **32** and shortened struts **28** in initial and expanded conditions. Each strut **28** is attached to two ductile hinges **32** at opposite ends. Each ductile hinge **32** has an instant center of rotation C_1, C_2 that is an effective pivot point for the attached strut **28**. Initially, during expansion the pivot point C_1 is displaced vertically by a distance d until C_1 is positioned even with C_2 as shown in FIG. **9***b*. When the array is expanded vertically, the axial struts **28** move in a circular arc with respect to the pivot points, as shown in FIG. **9***b*. It can be seen that the horizontal distance e between pivot points C_1 and C_2 actually increases initially, reaching a maximum e_{max} when the two points are on the same horizontal axis as shown in FIG. **9***b*. As the vertical expansion continues, the device compresses axially back to its original length. Only when vertical expansion of the array continues beyond the point where the horizontal distance e between C_1 and C_2 is the same as the original horizontal distance e does the overall length of the array actually begin to contract. For the stent shown in FIG. **2**, for example, approximately ⅓ of the total circumferential expansion has been accomplished by the time the configuration of FIG. **9***b* is reached, and the stent exhibits very low axial contraction.

This ability to control axial contraction based on hinge and strut design provides great design flexibility when using ductile hinges. For example, a stent could be designed with zero axial contraction.

An alternative embodiment that illustrates the trade off between crush strength and axial contraction is shown in FIG. **10**. FIG. **10** shows a portion of a tissue supporting device **70** having an array of struts **72** and ductile hinges **74** in the unexpanded state. The struts **72** are positioned initially at an angle θ_1 with respect to a longitudinal axis X of the device. As the device is expanded radially from the unexpanded state illustrated in FIG. **10**, the angle θ_1 increases. In this case the device contracts axially from the onset of vertical expansion throughout the expansion. Once the device has been completely expanded the final angle θ_1 made by the strut **72** with the horizontal will be much greater than the angle θ in the device of FIGS. **8***a* and **8***b*. As shown previously, a higher final strut angle θ_1, can significantly increase crush strength and decrease circumferential recoil of the stent structure. However, there is a trade off between increased crush strength and increase in axial contraction.

According to one example of the present invention, the struts **72** are positioned initially at an angle of about 0° to 45° with respect to a longitudinal axis of the device. As the device is expanded radially from the unexpanded state illustrated in FIG. **10**, the strut angle increases to about 20° to 80°.

According to one alternative embodiment of the present invention, the expandable tissue supporting device can also be used as a delivery device for certain beneficial agents including drugs, chemotherapy, or other agents. Due to the structure of the tissue supporting device incorporating ductile hinges, the widths of the struts can be substantially larger than the struts of the prior art devices. The struts due to their large size can be used for beneficial agent delivery by providing beneficial agent on the struts or within the struts. Examples of beneficial agent delivery mechanisms include coatings on the struts, such as polymer coatings containing beneficial agents, laser drilled holes in the struts containing beneficial agent, and the like.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention.

What is claimed is:

1. An expandable medical device comprising:

a plurality of elongated beams, the plurality of elongated beams joined together to form a substantially cylindrical device which is expandable from a first diameter to a second diameter, the plurality of elongated beams each having a beam width in a circumferential direction; and

a plurality of ductile hinges connecting the plurality of beams together in the substantially cylindrical device, the ductile hinges having a hinge thickness and a substantially constant width in a circumferential dimension along a portion of a hinge length which is at least ⅓ a total hinge length, wherein the hinge width is smaller than the hinge thickness and the hinge width is smaller than the beam width such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed.

2. The expandable medical device according to claim **1**, further comprising an abrupt transition between each of the elongated beams and each of the ductile hinges.

3. The expandable medical device according to claim **1**, further comprising a plurality of axial slots between adjacent

elongated beams and a plurality of circumferential slots, wherein the plurality of ductile hinges are each formed between an axial slot and a circumferential slot.

4. The expandable medical device according to claim 3, wherein the ductile hinges are formed at opposite ends of the circumferential slots.

5. The expandable medical device according to claim 1, wherein the ductile hinges are each in the shape of a curved prismatic beam.

6. The expandable medical device according to claim 1, wherein expansion of the substantially cylindrical device from the first diameter to the second diameter which is at least two times the first diameter results in substantially no axial contraction.

7. The expandable medical device according the claim 1, further comprising a geometric deflection limiting feature for limiting an amount of bending of the ductile hinges.

8. The expandable medical device according to claim 7, wherein the geometric deflection limiting feature is a V-shaped notch having side surfaces which contact each other when a maximum amount of bending is reached.

9. The expandable medical device according to claim 1, wherein the plurality of elongated beams extend substantially axially and a plurality of circumferential beams are each connected at first and second ends to one of the elongated beams by a ductile hinge.

10. The expandable medical device according to claim 1, wherein the hinge width is no greater than 60% of the hinge thickness.

11. The expandable medical device according to claim 1, wherein the hinge thickness is over 2 times larger than the hinge width.

12. The expandable medical device according to claim 1, wherein all of the ductile hinges have the same dimensions.

13. The expandable medical device according to claim 1, wherein the hinge width is at least 50% smaller than the beam width.

14. The expandable medical device according to claim 1, wherein the device is expandable by a balloon catheter pressurized by an inflation pressure of 1 to 5 atmospheres.

15. An expandable medical device comprising:

a plurality of elongated beams, the plurality of elongated beams joined together to form a substantially cylindrical device which is expandable from a first diameter to a second diameter, the plurality of elongated beams each having a beam width in a circumferential direction; and

a plurality of ductile hinges connecting the plurality of beams together in the substantially cylindrical device, the ductile hinges having a substantially constant width in a circumferential dimension along a portion of a hinge length which is at least ⅓ a total hinge length, wherein the hinge width is smaller than the beam width such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed, each of the ductile hinges being in the shape of a curved prismatic beam having first and second arcuate surfaces facing the same direction with the second arcuate surface being larger than the first arcuate surface, the curved prismatic beams being positioned such that during expansion tensile strain is distributed along the second arcuate surface of the curved prismatic beam.

16. An expandable medical device comprising:

a plurality of elongated beams, the plurality of elongated beams joined together to form a substantially cylindrical device which is expandable from a first diameter to a second diameter, the plurality of elongated beams each having a beam width in a circumferential direction; and

a plurality of ductile hinges connecting the plurality of beams together in the substantially cylindrical device, the ductile hinges having a substantially constant width in a circumferential dimension along a portion of a hinge length which is at least ⅓ a total hinge length, wherein the hinge width is smaller than the beam width such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed, the plurality of elongated beams being formed of wire and the plurality of ductile hinges being reduced diameter portions of the wire.

17. An expandable medical device comprising:

a cylindrical tube;

a plurality of axial slots formed in the cylindrical tube in a staggered arrangement to define a network of elongated struts, the elongated struts being axially displaced from adjacent struts and having a strut width in a circumferential direction; and

a plurality of ductile hinges formed between the elongated struts, the ductile hinges having a hinge thickness and a substantially constant width in a circumferential dimension along a portion of a hinge length which is at least ⅓ a total hinge length, wherein the hinge width is smaller than the hinge thickness and the hinge width is smaller than the strut width such that as the device is expanded from a first diameter to a second diameter the ductile hinges experience plastic deformation while the struts are not plastically deformed, the ductile hinges allowing the cylindrical tube to be expanded from the first diameter to the second diameter by deformation of the ductile hinges, the ductile hinges being asymmetrically configured to reach a predetermined strain level upon a first percentage expansion and to reach the predetermined strain level upon a second percentage of compression, wherein the first percentage is larger than the second percentage.

18. The expandable medical device according to claim 17, wherein the hinge width is less than ⅔ the strut width.

19. The expandable medical device according to claim 18, wherein a transition between the cross sectional area of the struts and the cross sectional area of the ductile hinges is an abrupt transition which extends less than 10 percent of a length of a strut.

20. The expandable medical device according to claim 17, wherein the plurality of ductile hinges are curved prismatic beams having a convex side surface and a concave side surface.

21. The expandable medical device according to claim 17, wherein a ratio of a length of the ductile hinges to a length of the axial struts is 1:6 or less.

22. The expandable medical device according to claim 17, further comprising a geometric deflection limiting feature for limiting an amount of bending of the ductile hinges.

23. The expandable medical device according to claim 17, wherein the ductile hinges are designed to deform plastically upon radial expansion or compression of the expandable medical device while the elongated struts experience no plastic deformation upon radial expansion or compression.

24. The expandable medical device according to claim 17, wherein the expandable medical device is formed of Nitinol, and the ductile hinges are designed to deform upon radial expansion or compression of the expandable medical device and can be returned to an original configuration by heating.

25. The expandable medical device according to claim 17, wherein the elongated struts include a beneficial agent for delivery to a patient.

26. An expandable medical device comprising:

a plurality of elongated beams having a substantially constant beam cross sectional area along a beam length and a beam width in a circumferential direction;

a plurality of ductile hinges connecting the plurality of beams together in a substantially cylindrical device which is expandable or compressible from a first diameter to a second diameter by plastic deformation of the ductile hinges, the ductile hinges having a hinge thickness and a substantially constant width in a circumferential dimension along a portion of a hinge length which is at least ⅓ a total hinge length, wherein the hinge width is smaller than the hinge thickness and the hinge width is smaller than the beam width such that as the device is expanded from the first diameter to the second diameter the ductile hinges experience plastic deformation while the beams are not plastically deformed; and

a plurality of deflection limiting members positioned at a plurality of the ductile hinges to limit the deflection at the ductile hinges.

27. The expandable medical device according to claim 26, wherein the deflection limiting members include angled side walls on opposite sides of the ductile hinges which engage one another to limit deflection of the ductile hinges.

28. The expandable medical device according to claim 27, wherein the deflection limiting members are V-shaped notches.

29. An expandable medical device which is visible in x-ray and fluoroscope images, the device comprising:

a plurality of struts arranged to form an expandable cylindrical tube, the struts having a strut width in a circumferential direction; and

a plurality of ductile hinges connecting the plurality of struts, wherein the struts and ductile hinges have a thickness in a radial direction of the cylindrical tube of at least 0.003 inches (0.0762 mm), the ductile hinges having a hinge thickness and a substantially constant width in a circumferential dimension along a portion of a hinge length which is at least ⅓ a total hinge length, wherein the hinge width is smaller than the hinge thickness and the hinge width is smaller than the strut width such that as the device is expanded from a first diameter to a second diameter the ductile hinges experience plastic deformation while the struts are not plastically deformed.

30. The expandable medical device according to claim 29, wherein the device is formed of stainless steel.

31. The expandable medical device according to claim 29, wherein the thickness of the struts and ductile hinges is at least 0.005 inches (0.127 mm).

* * * * *

EXHIBIT E

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10-Q

FORM 10-Q
Filed on 08/09/2006 - Period: 06/30/2006
File Number 000-51066

7. Subsequent Events

On August 1, 2006, the Company completed a follow-on public offering of 3,500,000 shares of its common stock at a public offering price of $27.50 per share. Net cash proceeds from the public offering are expected to be approximately $89.9 million, after deducting underwriting discounts and other estimated offering expenses. The Company and a selling stockholder have granted the underwriters a 30-day option to purchase up to an aggregate of 525,000 additional shares of common stock to cover over-allotments, if any, of which 75,000 shares would be sold by the Company if the over-allotment option is exercised in full.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in this Quarterly Report on Form 10-Q in greater detail under Part II, Item 1A below. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Overview

We develop innovative controlled vascular drug delivery technologies. We have primarily focused on the development of drug-eluting stents to treat coronary artery disease. Specifically, our efforts have initially focused on the development and commercialization of our cobalt chromium paclitaxel-eluting coronary stent system, CoStar®, for the treatment of restenosis. In February 2006, our CoStar stent received CE Mark approval in the European Union, and we have commercially launched our CoStar stent in many of the countries in the European Union through our distributor, Biotronik AG.

Historically, we have devoted substantially all of our resources to developing our stent platform, raising capital and preparing for the commercialization of our CoStar stent. We have pursued a clinical development strategy of demonstrating that our CoStar stent is safe and effective, that the drug inlay design of our CoStar stent permits us to control drug release kinetics, and that drug release kinetics can have a direct impact on clinical outcomes. Recently, our clinical development strategy has been focused on establishing the basis for regulatory approval of our CoStar stent in the United States and demonstrating that our cobalt chromium pimecrolimus-eluting coronary stent system, Corio™, and our cobalt chromium pimecrolimus- and paclitaxel-eluting coronary stent system, SymBio™, are safe and effective.

With respect to potential U.S. regulatory approval of our CoStar stent, we submitted an investigational device exemption, or IDE, application to the U.S. Food and Drug Administration, or FDA, in the first quarter of 2005 for our U.S. pivotal clinical trial, COSTAR II, and in March 2005, we received conditional approval of our IDE application. The first patient was enrolled in the trial in May 2005. In December 2005, we received approval from the FDA to expand enrollment in the COSTAR II

trial to the full cohort of 1,700 patients, and we completed enrollment of all 1,700 patients in April 2006. If the clinical trial proceeds as scheduled and the outcome of this clinical trial is favorable, we anticipate submitting an application for marketing approval with the FDA in 2007 and, if the FDA agrees that we have established the safety and effectiveness of our CoStar stent, receiving regulatory approval for our CoStar stent in the United States in late 2007 or early 2008. We could be delayed by adverse results or regulatory complications, and we may never achieve U.S. regulatory approval.

If we obtain the necessary regulatory approvals, we plan to pursue commercialization of our CoStar stent in the United States with our own sales force and internationally through distribution arrangements. Our wholly-owned subsidiary, Conor Medsystems Ireland Limited, or Conor Ireland, entered into an agreement with Biotronik AG to distribute our CoStar stent in countries outside of the United States, Japan, Australia, New Zealand and Korea and certain other countries. On April 27, 2006, Conor Ireland entered into an agreement with Interventional Technologies Limited, or IVT, under which IVT is the exclusive distributor of the Company's CoStar stent in India, Pakistan, Bangladesh, Sri Lanka, Kenya, and Tanzania. This agreement supersedes and replaces the agreement entered into with IVT in July 2004. Conor Ireland also entered into agreements with affiliates of St. Jude Medical, Inc. to distribute our CoStar stent in Japan, Korea, New Zealand and Australia. A decision to seek regulatory approval of, or to sell, our CoStar stent has not yet been made in respect to all of these countries.

In March 2006, pursuant to the terms of our agreement with Novartis Pharma AG, we exercised our option to obtain a worldwide, non-exclusive license from Novartis to develop, manufacture and commercialize products that use our vascular delivery stent systems, including our drug-eluting reservoir-based cobalt chromium stent, for the local delivery of pimecrolimus. In May 2006, we initiated the GENESIS trial, which is a multi-center, randomized, three-arm non-inferiority pivotal study designed to compare our Corio, our SymBio, and our CoStar stent, and we expect to begin enrollment in the third quarter of 2006. In May 2006, we initiated the RAPID trial, which is a prospective, open-label, multi-center registry designed to evaluate our Corio stent for safety and effectiveness, and we expect to begin enrollment in the fourth quarter of 2006. In addition, we entered into a feasibility agreement with Biotronik to evaluate a bioresorbable reservoir-based stent incorporating Biotronik's absorbable metal to enable tailored drug release kinetics for the treatment of restenosis and other vascular disorders. We are also investigating the applicability of our stent technology to the treatment of an acute myocardial infarction, or AMI, commonly known as a heart attack.

We were incorporated in Delaware in October 1999 and have a limited operating history. We have incurred net losses each year. We anticipate that we will continue to incur net losses for the next several years as we develop new products, expand our clinical development team and corporate infrastructure and, assuming we receive FDA approval, prepare for the potential U.S. commercialization of our CoStar stent. We currently have no products approved for sale in the United States. We have financed our operations primarily through private placements of preferred stock and convertible promissory notes, as well as through our public offerings of our common stock. On August 1, 2006, we completed a follow-on public offering of 3,500,000 shares of our common stock at a public offering price of $27.50 per share. Net cash proceeds from the public offering are expected to be approximately $89.9 million, after deducting underwriting discounts and other estimated offering expenses.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles for interim financial reporting. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate estimates, including those related to stock-based compensation and clinical trial accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There has been no significant change in our critical accounting policies or estimates from those policies or estimates disclosed under the heading "Critical Accounting Policies and Significant Judgments and Estimates" in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2005, filed with the SEC on March 16, 2006, except for employee stock-based compensation related to our adoption of a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123R.

Stock-Based Compensation – Adoption of SFAS 123R

We adopted SFAS 123R effective January 1, 2006 which requires the recognition of stock-based compensation at fair value in our statements of operations. We adopted SFAS 123R under the modified prospective transition method and therefore we have not restated results for prior periods. The preparation of financial statements in accordance with U.S. generally accepted accounting principles requires us to estimate the fair value of the stock options granted. While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options

EXHIBIT F

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EXHIBIT G

REDACTED

EXHIBIT H

in the second quarter of 2006. If our COSTAR II trial proceeds as scheduled and the outcomes of this clinical trial are favorable, we anticipate submitting an application for marketing approval with the FDA in 2007 and, if FDA agrees that we have established the safety and effectiveness of our CoStar stent, receiving regulatory approval for our CoStar stent in the United States in late 2007 or early 2008. We could be delayed by adverse results or regulatory complications, and we may never achieve regulatory approval in the United States.

If we obtain the necessary regulatory approval, we plan to pursue commercialization of our CoStar stent in the United States with our own sales force and internationally through distribution arrangements. We entered into an agreement with Biotronik AG to distribute our CoStar stent in countries outside of the United States, Japan, Australia, New Zealand and Korea and certain other countries. We entered into an agreement with Interventional Technologies, Pvt., Ltd., or IVT, to distribute our CoStar stent in India, Pakistan, Bangladesh, Sri Lanka, Kenya and Tanzania. In November 2004, we entered into agreements with affiliates of St. Jude Medical, Inc. to distribute our CoStar stent in Japan, Korea, New Zealand and Australia. A decision to seek regulatory approval of, or to sell, our CoStar stent has not yet been made in respect to all of these countries. In 2005, we began commercializing our CoStar stent in certain countries outside of the United States, the European Union and Japan pursuant to these distribution agreements.

In March 2006, pursuant to the terms of our agreement with Novartis Pharma AG, we exercised our option to obtain a world-wide, non-exclusive license from Novartis to develop, manufacture and commercialize products that use our vascular delivery stent systems, including our drug-eluting reservoir-based cobalt chromium stent, for the local delivery of pimecrolimus. In 2006, we expect to initiate a three-arm pilot study to evaluate the effectiveness of our pimecrolimus-eluting reservoir-based cobalt chromium stent and our pimecrolimus- and paclitaxel-eluting reservoir-based cobalt chromium stent for the treatment of restenosis. In addition, we continue to evaluate a bioresorbable reservoir-based stent that we designed incorporating Biotronik's absorbable metal to enable tailored drug release kinetics for the treatment of restenosis and other vascular disorders. We are also investigating the applicability of our stent technology to the treatment of an acute myocardial infarction, or AMI, commonly known as a heart attack.

We were incorporated in Delaware in October 1999 and have a limited operating history. To date, we have not generated significant revenues, and we have incurred net losses each year. We anticipate that we will continue to incur net losses for the next several years as we develop new products, expand our clinical development team and corporate infrastructure and pursue the commercialization of our CoStar stent. We have financed our operations primarily through private placements of preferred stock and convertible promissory notes, as well as through our initial public offering of our common stock. In July and August 2004, we raised aggregate net cash proceeds of $38.9 million in a private placement of 6,711,431 shares of our Series E convertible preferred stock. In December 2004 and January 2005, we raised net cash proceeds of $78.1 million, in our initial public offering of our common stock. We currently have no products approved for sale in the United States.

Financial Operations

Product Sales

In 2005, we began commercializing our CoStar stent in certain countries outside of the United States, the European Union and Japan. Prior to February 2005, we had not generated any revenues from the sale of our stents. In February 2006, our CoStar stent received CE Mark approval in the European Union, and we commercially launched our CoStar stent in the European Union through our distributor, Biotronik AG. As a result of the commercial launch of our CoStar stent in many of the countries in the European Union we expect product revenues to significantly increase over current levels, and we continue to expect that revenues from the sales of our CoStar stent will fluctuate from quarter to quarter.